

REMARKS

Claims 1-7, 11-17, 20, 22, 24-27, and 29 are all the claims pending in the application. Claims 1, 2, 11-13 and 20 have been amended, and claims 9 and 10 are canceled. Support for the amendments to claims can be found throughout the specification and, specifically, in at least claims 9-10 and paragraphs [0014], [0047]-[0055] of U.S. Published Application No. 2003/0017447. Accordingly, no new matter has been introduced by way of these amendments.

Claim Rejections - 35 U.S.C. § 103(a)

The Final Office Action of 7 September 2007 rejected claims 1-7, 9-17, 20, 22, 24, 25 and 29 as allegedly being unpatentable over Chang et al (US 5,270,169) in view of Walter et al., (Stimulation of human cytotoxic T cells with HIV-1-derived peptides presented by recombinant HLA-A2 peptide complexes, International Immunology, vol. 9, No: 3, pp. 451-459, 1997).
Office Action of 7 September 2007, page 3.

Applicants have amended claim 1, 2 and 20 to better capture the envisioned commercial embodiments. Applicants assert that the amendment to claim 1, 2 and 20 render moot all outstanding claim rejections because the cited arts fail to teach each and every element of the presently claimed invention. Specifically, the cited references, Chang and Walter, failed to teach detecting binding or absence of binding of antibodies to only immobilized recombinant MHC molecules (claim 1) and to only immobilized recombinant HLA molecules (claim 2). The references also failed to teach “detecting anti-MHC antibodies bound to only recombinant MHC molecules (claim 20).” Claims 1-7, 9-17, 25 and 29 depend directly or indirectly from claim 1 or 2, and claims 22-24 from claim 20.

Chang does not teach or suggest detecting binding or absence of binding of antibodies to only immobilized recombinant MHC or HLA molecules as Chang does not even have any recombinant molecule, and Chang immobilized C1q molecule, instead of HLA antigens.

Walter does not teach or suggest detecting binding or absence of binding of antibodies either to only immobilized recombinant MHC molecules or to only immobilized recombinant HLA molecules as Walter never immobilized the recombinant molecules on a support other than a cell. A cell surface contains other molecules that can bind to other antibodies, and non-MHC or non-HLA bound antibodies will be detected. *See* [0014] of U.S. Published Application No. 2003/0017447.

By the same argument above, the references also failed to teach detecting anti-MHC antibodies bound to only immobilized recombinant MHC molecules (claim 20).

To establish *prima facie* obviousness of a claimed invention, all the cited references must recite all the claim limitations. *In re Royka*, 490 F.2d 981, 984 (CCPA 1974). For the reasons previously presented above, Applicants contend that neither Chang, Walter, nor the other cited references, alone or in combination, teach or suggest all the claim limitations of the invention, either explicitly or inherently. In particular, these references do not expressly or inherently teach detecting binding or absence of binding of antibodies to only immobilized recombinant MHC or HLA molecules. Thus, these references do not support a *prima facie* case of obviousness. Further, because the cited references do not teach all of the claim limitations, there can be no reasonable expectation of success in combining the cited references to arrive at the claimed invention.

In addition, the Office Action fails to establish a reason as to why one of skill would alter or combine the references in the suggested manner. As the Supreme Court recently discussed,

the “apparent reason to combine the known elements in a fashion claimed by the [claims] at issue ... should be made explicit.” *KSR Int’l Co. v. Teleflex, Inc.* No 04-1350 slip op. at 14 (U.S. Apr. 30, 2007). The Office Action alleges that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a recombinant HLA antigen and the corresponding reagents as taught by Walter et al into the method of Chang et al because Chang et al teaches that the HLA antigen can be synthetic HLA antigen and Walter shows that recombinant HLA antigens can be used to detect allele specific antibodies and that the recombinant complexes contain native epitopes, consistent with the presence of correctly folded molecular complexes.” *Office Action of 7 September 2007*, page 4. However, even if Walter’s recombinant HLA antigens are incorporated into the method of Chang, such combination would not yield the present invention. Chang involves the detection of HLA immune complexes through binding of C1q moieties attached to solid supports. Chang uses HLA antigens in order to facilitate immune complex formation for C1q binding. Accordingly, adding recombinant HLA antigens taught by Walter to the method in Chang results in a generic C1q-bound immune complex that happens to contain recombinant HLA antigens. That is not what is being claimed. Moreover, the Office Action is silent as to why one would immobilize a recombinant HLA antigen, instead of C1q protein to detect MHC antibodies. Indeed, there is no reason that one of skill in the art would have in combining the cited references.

In conclusion, Applicants assert that the cited references fail to render obvious the presently claimed invention. Specifically, the references fail to teach each and every element of the claimed invention and there is no reasonable expectation of success in combining the claimed references. In addition, the Office Action fails to provide any reason as to why one of skill in the

art would combine or alter the references in the manner suggested in the Action. Applicants respectfully request reconsideration and withdrawal of the obviousness rejection.

Finally, claims 24-27 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Chang in view of Walter as applied to claims 1-7, 9-17, 20 and 22-24 above, and further in view of Luxembourg et al. *Office Action of 7 September 2007*, page 4. Applicants respectfully note that claim 24 is a dependent claim from claim 22, describing a spherical bead as a solid support, and does not have any feature of biotin fused with the MHC or HLA molecules, unlike claims 25-27. Applicants believe this rejection was intended only for claims 25-27.

Clarification is requested.

For the reasons set forth above in relation to the patentability of the claims from which these claims depend, Applicants submit that the primary and secondary cited references do not make obvious the detection of antibodies bound to only immobilized recombinant MHC molecules. The addition of the teachings of Luxembourg et al. does not overcome the deficiencies of the other references. Accordingly, Applicants assert that the combination of cited references fails to render obvious the claimed invention.

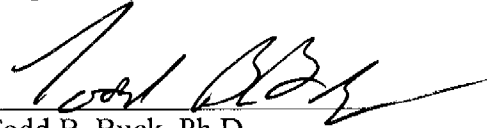
Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Todd B. Buck, Ph.D.
Registration No. 48,574

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/142565

57904

CUSTOMER NUMBER

Date: December 7, 2007